Life Spine®

K062643

Special 510(k) Summary of Safety and Effectiveness

Special 510(k) Summary - KINETIC™ Anterior Cervical Plate

NOV 16 2006

**Submitted By:** Life Spine
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**510(k) Contact:** Erin Malloy
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**Date Prepared:** September 5, 2006

**Trade Name:** KINETIC™ Anterior Cervical Plate

**Common Name:** Spinal Fixation System

**Classification:** Spinal Invertertebral Body Fixation Orthosis
CFR 888.3060
Class II

**Device Product Code:** KWQ

**Predicate Device:** NEO™ Anterior Cervical Plate System K040844 and other predicate devices

**Device Description:**

The KINETIC™ Anterior Cervical Plate consists of various sizes of anterior cervical bone plates, screws and screw locking tabs. Components are available in a variety of sizes to fit patient anatomy. All components are manufactured from implant grade titanium alloy 6A1-4V ELI per ASTM F-136. The KINETIC™ Anterior Cervical Plate components will be supplied clean and "NON-STERILE".

**Intended Use of the Device**:

The KINETIC™ Anterior Cervical Plate is indicated for use in temporary stabilization of the anterior spine from C2 to T1 during the development of cervical spinal fusions in patients with:

1. Degenerative disc disease, DDD (as defined by neck pain of discogenic origin with degeneration of disc confirmed by patient history and radiographic studies);
2. Spondylolisthesis
3. Trauma (including fractures or dislocations);

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4. Spinal cord stenosis;
5. Deformity or curvatures (i.e. kyphosis, lordosis or scoliosis);
6. Tumors;
7. Pseudarthrosis;
8. Failed previous fusions.

**WARNING: This device is not approved for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.**

**Material:**

The KINETIC™ Anterior Cervical Plate is manufactured from medical grade titanium alloy described by ASTM F136 (Ti 6AL-4V-ELI).

**Performance Data:**

Biomechanical testing in accordance with ASTM F1717 was conducted to demonstrate substantial equivalence.

**Substantial Equivalence:**

The KINETIC™ Anterior Cervical Plate was shown to be substantially equivalent to previously cleared devices in indications for use, design, function, and materials used.



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DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

NOV 16 2006

Life Spine
% Ms. Erin Malloy
Project Engineer
2400 Hassell Road, Suite 370
Hoffman Estates, Illinois 60195

Re: K062643
Trade/Device Name: KINETIC™ Anterior Cervical Plate
Regulation Number: 21 CFR 888.3060
Regulation Name: Spinal intervertebral body fixation orthosis
Regulatory Class: Class II
Product Code: KWQ
Dated: October 13, 2006
Received: October 17, 2006

Dear Ms. Malloy:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Office of Compliance at (240) 276-0120. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (240) 276-3150 or at its Internet address http://www.fda.gov/cdrh/industry/support/index.html.

Sincerely yours,

Mark N. Melkerson
Director
Division of General, Restorative,
and Neurologic Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

Life Spine®

# Indications for Use

**510(k) number (if known):** K062643

**Device Name:** KINETIC™ Anterior Cervical Plate

The KINETIC™ Anterior Cervical Plate System is intended for anterior interbody screw fixation of the cervical spine. This system is indicated for use in temporary stabilization of the anterior spine from C2 to T1 during the development of a cervical spinal fusions in patients with degenerative disc disease (as defined by neck pain of discogenic origin with degeneration of disc confirmed by patient history and radiographic studies); spondylolisthesis; trauma (including fractures or dislocations); spinal cord stenosis; deformity or curvatures (i.e. kyphosis, lordosis or scoliosis); tumors; pseudarthrosis; and / or failed previous fusions.

**WARNING: This device is not approved for screw attachment or fixation to the posterior elements (pedicles) of the cervical, thoracic, or lumbar spine.**

Prescription Use __x__ (Part 21 CFR 801 Subpart D) And/Or Over-the-Counter Use ____ (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

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**(Division Sign-Off)**
**Division of General, Restorative, and Neurological Devices**

**510(k) Number** K062643

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